4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0487]

Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice, published in the *Federal Register* of March 1, 2023, establishing a public docket and requesting information and comments. FDA is reopening the comment period to update comments and to receive any new information.

DATES: FDA is reopening the comment period on the notice published March 1, 2023 (88 FR 12943). Either electronic or written comments must be submitted by [INSERT DATE 60 AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2023-N-0487 for "Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4162, Silver Spring, MD 20993, 240-402-7930, Elizabeth.Giaquinto@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of March 1, 2023 (88 FR 12943), FDA established a public docket to solicit comments on the "Discussion Paper: Artificial Intelligence in Drug Manufacturing." The discussion paper presents areas for consideration and policy development identified by the Center for Drug Evaluation and Research (CDER) scientific and policy experts associated with application of artificial intelligence to pharmaceutical manufacturing. The discussion paper includes a series of questions to stimulate feedback from the public, including CDER and the Center for Biologics Evaluation and Research stakeholders.

Interested persons were originally given until May 1, 2023, to comment on the content of the discussion paper.

Following publication of the March 1, 2023, notice, FDA has decided to reopen the public docket to allow interested persons additional time to comment on the discussion paper. We note that there is also a public workshop organized by FDA and the Product Quality Research Institute entitled "Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing: An Opportunity for Stakeholder Engagement," which is scheduled for September 26 and 27, 2023 (https://pqri.org/fda-pqri-aiworkshop/).

Dated: September 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-20902 Filed: 9/26/2023 8:45 am; Publication Date: 9/27/2023]